RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK REUSABLE HOT BIOPSY FORCEPS

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Device Description:
The Wilson-Cook Reusable Hot Biopsy Forceps is comprised of a spool and stationary thumb-ring handle, electrosurgical plug, flush port, coil spring body shaft and forceps cups. The forceps cups are 2.5 mm and the device has a length of 230 cm. The coil spring body is covered with a FEP heat shrink electrical insulation. The electrosurgical plug is located on the spool portion of the handle and is used for connection to the appropriate electrosurgical unit. The flush port is located at the base of the handle and is used for flushing during the cleaning process.

Trade Name:	Wilson-Cook Hot Maxx Reusable Hot Biopsy Forceps
Common/Usual Name:	Reusable Hot Biopsy Forceps
Classification Name/Code:	Forceps, Biopsy, Electric/78 KGE
Classification:	FDA has classified similar devices as Class II, as per 21 CFR § 876.4300. This device falls within the purview of the Gastroenterology and Urology Device Panel.
Performance Standards:	To the best of our knowledge, performance standards for this device do not exist.
Intended Use:	Used endoscopically in conjunction with monopolar electrosurgical current to obtain gastrointestinal mucosal tissue biopsies for microscopic examination, and for the removal of sessile polyps.

Predicate Device:

[illegible]	[illegible]	[illegible] (K) [illegible] NUMBER
Portlyn Reusable Hot Biopsy Forceps (K9)	Medsource (formerly Portlyn)	K970083

Substantial Equivalence:
The Wilson-Cook Reusable Hot Biopsy Forceps is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use.

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK REUSABLE HOT BIOPSY FORCEPS

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

[illegible] CHARACTERISTIC	[illegible] Subject of 510(k)	[illegible] K930085
Intended Use	Used endoscopically in conjunction with monopolar electrosurgical current to obtain gastrointestinal mucosal tissue biopsies for microscopic examination, and for removal of sessile polyps.	Used for removal of histological samples from the inner walls of the intestines and for performing associated electrocautery.
Sterility	Non-Sterile, Reusable	Non-Sterile, Reusable

Testing: Biocompatibility has been established for the patient contacting materials through a history of use in the Portlyn Reusable Hot Biopsy Forceps. This product line has been subjected to Design Verification. During Design Verification, visual, dimensional and functional testing to ensure the performance, design integrity for this product line was conducted. All results obtained during our Design Verification met our predetermined acceptance criteria for this product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2000

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K000086
Wilson-Cook Reusable Hot Biopsy Forceps
Dated: January 7, 2000
Received: January 12, 2000
Regulatory Class: II
21 CFR §876.4300/Procode: 78 KGE

Dear Ms. Posner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K000086

Device Name: Wilson-Cook Reusable Hot Biopsy Forceps

Indications for Use:

Used endoscopically in conjunction with monopolar electrosurgical current to obtain gastrointestinal mucosal tissue biopsies for microscopic examination, and for the removal of sessile polyps.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000086